

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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OMB
Display Date 3-30-00
Publication Date 3-31-00
Certifier S. H. Reese

Food and Drug Administration

[Docket No. 99N-5222]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of a Claim for GRAS Exemption Based on a GRAS Determination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notice of a Claim for GRAS Exemption Based on a GRAS Determination (OMB No. 0910-0342—Extension)

Section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) establishes a premarket approval requirement for “food additives;” section 201(s) of that act (21 U.S.C. 321(s)) provides an exemption from the definition of “food additive” and thus from the premarket approval requirement, for uses of substances that are generally recognized as safe (GRAS) by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the GRAS claim, and the agency’s response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

Description of Respondents: Manufacturers of Substances Used in Food and Feed.

In the **Federal Register** of December 17, 1999 (64 FR 70714 at 70715), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
170.36(c)(1)(v) ²	50	1	50	15	750
570.36(c)(1)(v) ²	10	1	10	15	150
Total					900

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

²Due to a clerical error, the CFR cites that appeared in table 2 of the FEDERAL REGISTER of December 17, 1999 (64 FR 70714) were incorrect. Table 2 of this document contains the correct CFR cite.

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule; between

January 1, 1999, and November 30, 1999, FDA received 23 notices. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: March 24, 2000



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

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